REMARKS

Claims 1-10, 14, 17 and 20-22 are in this application. Claims 1-10 are withdrawn. Claims 14 and 17 have been amended. Claims 11-13, 15, 16, 18 and 19 have been cancelled.

Claims 14 and 17 are being amended to insert "human" before "subject"; insert "immunological" before "recurrent spontaneous abortion", replace "spouse" with " male mate" and to include that chromosome No. 2 is isolated from a human. In addition, these claims are being amended to include that said chromosome No. 2 is isolated from somatocytes in M phase. Support for these amendments is found throughout the specification. Support for immunological recurrent spontaneous abortion is found *inter alia* on pages 9 and 11 of the specification. Support for isolating chromosome No. 2 from cells in the M phase in found on page 13 of the specification.

Claim 14 was objected to because of the phrases " subject in need of treatment", and " fibronectin encoding gene" These phrases have been deleted from claim 14. In view of these amendments and other amendments made to claim 14, the objection to claim 14 is moot.

The Examiner has rejected claims 14-22 under 35 USC 112, first paragraph. This is respectfully traversed.

As explained above, claims 14 and 17 have been amended to define the recurrent spontaneous abortion as immunological recurrent spontaneous abortion. Applicant draws the examiner's attention to page 15, lines 8-10 of the specification where it is stated that immunological RSA is early secondary recurrent spontaneous abortion wherein the titer of the antinuclear antibody in serum is higher than 1:64. Therefore, it is applicant's position that it is not necessary to amend the claims to include that the specific antinuclear antibodies are greater than 1:64.

The examiner alleges that the isolation of chromosome 2 alone is not reported or proven in the description. Reference is made to the following paragraphs of the application that further support that the claims are enabled.

On page 11, first paragraph, of the present application, it is disclosed in experimental data that *"injection, to a subject suffered from immunological early secondary RSA before pregnancy, of chromosome No. 2 containing FN encoding gene derived from her spouse can effectively lower the level of antinuclear antibody against chromosome No. 2 in peripheral blood of the subject.* " Data is provided in table 2 in the present application.

In the third paragraph of page 16 of the present application, it is disclosed that *"isolated chromosome No. 2 or fragment thereof is preferably used in the present invention. "*

In the fourth paragraph of page 16 of the present application teaches a method for isolating chromosome No. 2 from peripheral blood lymphocytes, encompassing isolating of total chromosomes *"by chemical or physical methods well known to a person skilled in the art"*, wherein *"hyposmosis is preferred"*, followed by further isolation of *"intact chromosome No.2"*, which *"can be further isolated by methods well known to a person skilled in the art such as density gradient centrifugation. "*

Example 3 discloses a specific example for preparing chromosome No.2 by hyposmosis (0.06 % KCl solution, see point (4)) and density gradient centrifugation (sucrose density gradient centrifugation. In light of the method disclosed in this application, a person skilled in the art would easily recognize that what was obtained from Example 3 is just chromosome No.2.

Furthermore, Examples 4-5 have proven the effects of such isolated chromosome No.2.

In addition, applicant provides further experimental proof in form of the attached Affidavit of the inventor of the present application, Mr. Fenglin Chen, that was filed in the corresponding European application, now granted, who states in item 3 of the Affidavit, *"that the product obtained from the procedure reported in Example 3 of the European Patent application No. 04712990.3 is substantially purified chromosome*

Item 4 of the Affidavit gives further evidence, showing a chromosome photograph of a chromosome suspension of *"an appropriate amount of the chromosome pellet obtained in step* 8", *"according to the method described in Example* 3 *of the present application"*. The Affidavit provides further evidence that *"based on chromosome morphology identification, the isolated and purified substance was substantially chromosome 2."*

In addition to Examples 4-5 of the present application, which prove the effects of such isolated chromosome No.2, Mr. Fenglin Chen further states in item 2 of the Affidavit that *"over 1000 RSA patients have been treated with this treatment and the clinical rate of success is about* 95%."

Therefore, based on the description and as explained in the Affidavit the isolation and beneficial effects of chromosome No.2 in the treatment of immunological RSA is established.

It is clear that the claims are enabled and it is respectfully requested that the rejection be withdrawn.

The examiner has rejected claims 15 and 18 under 35 USC 112, second paragraph. This is respectfully traversed.

However, in view of the cancellation of claims 15 and 18, it is respectfully requested that this rejection be withdrawn.

The examiner has rejected claims 14 and 15 as being anticipated by Gatenby. This is respectfully traversed.

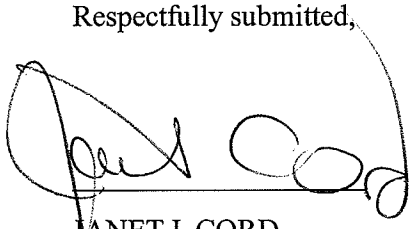
In order for a reference to anticipate a claim, each element of the claim must be disclosed in the reference. There is no disclosure in the cited reference of "A method for treating a human subject with immunological recurrent spontaneous abortion comprising administering to said subject a therapeutically effective amount of isolated chromosome No. 2 wherein said chromosome is obtained from a human male mate of said subject, wherein said chromosome No. 2 is isolated from somatocytes in M phase.

Furthermore, as disclosed on Table 4 of this application, the "cure rate" using the method of this invention was > 95% while the use of lymphocyte immunotherapy derived from a spouse is 62%. This is a statistically significant difference. The percentage of successful gestations obtained using immunotherapy is consistent with the results obtained in Gatenby which was 68%.

Gatenby does not anticipate claim 14 and it is respectfully requested that this rejection be withdrawn.

It is submitted that the present application is in condition for allowance and favorable consideration is respectfully requested.

Respectfully submitted,



JANET I. CORD
LADAS & PARRY LLP
26 WEST 61ST STREET
NEW YORK, NEW YORK 10023
REG. NO.33778 (212)708-1935

AFFIDAVIT OF MR. FENGLIN CHEN

I, Fenglin Chen, of 18 Dongsanhuan Zhonglu, Beijing, China declare and state that:

1. I am the president of Beijing Xinjing Antai Medical and Technology Service Limited Corp., the applicant of the European Patent Application no. 04712990.3, and the inventor of the same patent application. I am also president of Xinjing Antai Maternity Hospital, an affiliate entity of the applicant. I hold a master degree in gynecology from University of Medical Sciences of China. I have been a gynecologist for about 24 years focusing on both clinical and research aspects.

2. I invented the treatment of recurrent spontaneous abortion (RSA) with purified chromosome 2. Over 1,000 RSA patients have been treated with this treatment and the clinical rate of success is about 95%.

3. I verify that the product obtained from the procedure reported in Example 3 of the European Patent Application No. 04712990.3 is substantially purified chromosome 2 as shown by the following Experiment A which was done under my supervision. Samples of such purified chromosome 2 were used in the clinical cases as reported in the patent application and my hospital practice.

4. Experiment A

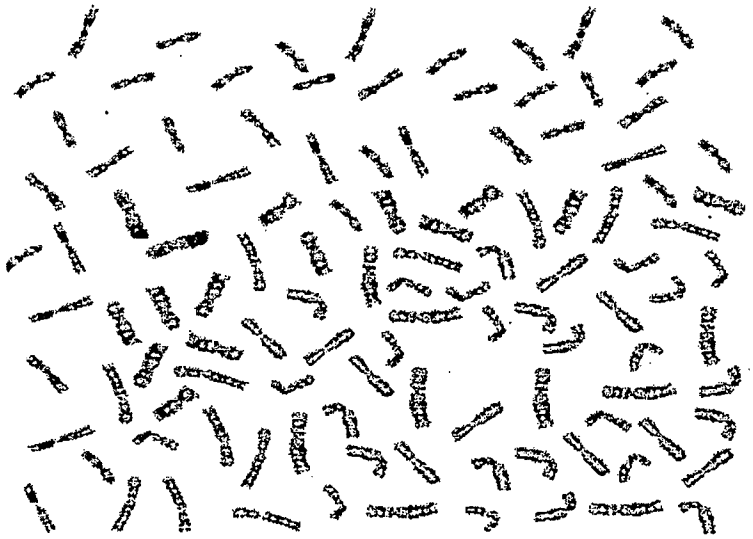
Purification:

Lymphocyte culturing and chromosome 2 purification were conducted according to the method described in Example 3 of the present patent application.

Identification:

An appropriate amount of the chromosome pellet obtained in step 8 was taken and

suspended in physiological saline. The chromosome suspension was applied onto a microscope slide, air dried, fixed with glacial acetic acid and stained with Giemsa reagent. The following chromosome photograph was achieved by observing and photographing with microscope OLYMPUS BS-51. Based on chromosome morphology identification, the isolated and purified substance was substantially chromosome 2.



By Fenglin CHEN
On January 9, 2008